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## **Treatment of nonalcoholic fatty liver disease: from adult trials to perspectives in the management of children and adolescents**

Doulberis, Michael ; Polyzos, Stergios A ; Papaefthymiou, Apostolis ; Katsinelos, Panagiotis ; Kiosses, Christos ; Kountouras, Jannis

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Drug name/ Category	Properties	Clinical Trial Phase (possible completion date*)	Trial ID
BMS-986036 <sup>a</sup>	Pegylated analogue of fibroblast growth factor 21	2 (1/2020) 2 (1/2020)	NCT03486912 NCT03486899
Elafibranor <sup>a</sup> (GFT505)	PPAR $\alpha/\delta$ agonist, insulin sensitizer, ameliorating hepatic inflammation, steatosis and fibrosis	2 (11/2020)**	NCT03883607
Gemcabene <sup>a</sup>	Dialkyl ether dicarboxylic acid with antihyperlipidemic activity	2 (8/2019)**	NCT03436420
GS0976 acetyl-CoA carboxylase (Firsocostat) <sup>a</sup>	Fatty acid metabolism key regulator, controlling the balance between <i>de novo</i> lipogenesis and fatty acid oxidation	2 (6/2020) 2 (10/2019)	NCT03987074 NCT03449446
Liraglutide <sup>a</sup>	Glucagon-like peptide-1 analogue, injectable drug, with shown efficacy to induce weight loss and lower glucose in obese patients; approved for T2DM and obesity	3 (12/2017) 4 (9/2023)	NCT02654665 NCT03648554
NGM282 (M70) <sup>a</sup>	Non-tumorigenic, engineered variant of fibroblast growth factor 21 (Receptors 1c, 4) reducing steatosis and lipotoxicity	2 (9/2020) 2 (9/2019)	NCT03912532 NCT02443116
Pioglitazone <sup>a</sup>	PPAR $\gamma$ activator, attenuating IR, steatosis, lobular inflammation, and fibrosis; approved for T2DM	4 (2/2019) 4 (9/2020) Cohort(7/2021)	NCT03796975 NCT03910361 NCT02815891
Saroglitazar <sup>a</sup>	PPAR- $\alpha/\gamma$ dual agonist; approved for hypertriglyceridemia in T2DM	2 (4/2020) 2 (10/2019) 2 (8/2019) 2 (9/2020)	NCT03639623 NCT03617263 NCT03061721 NCT03863574
Pemafibrate (K-877) <sup>a</sup>	Selective PPAR- $\alpha$ modulator	2 (2/2020)	NCT03350165
BI 1467335 <sup>b</sup>	Promoter of leukocyte recruitment in the liver, with monoamine oxidase activity, insulin-like effects, and initiation of oxidative stress	2 (6/2019)	NCT03166735
Cilofexor (GS-9674) <sup>b</sup>	Selective non-bile acid FXR agonist, designed to avoid the side effects of obeticholic acid	2 (8/2019) 2 (10/2019)	NCT02781584 NCT03449446
Emricasan <sup>b</sup>	Irreversible pan-caspase inhibitor	2 (8/2019)	NCT03205345
Losartan <sup>b</sup>	Angiotensin II receptor antagonist; approved for arterial hypertension	2 (04/2020)**	NCT03467217
Metadoxine <sup>b</sup>	Antioxidant, source of glutathione, capable of inhibiting adipocyte differentiation, limiting hepatic lipid accumulation and exerting antifibrotic properties	4 (1/2020)	NCT02051842
Pentoxifylline <sup>b</sup>	Anti-oxidant/anti-inflammatory properties	Not applicable (6/2016)	NCT02231333
Tipelukast (MN-001) <sup>b</sup>	A leukotriene receptor antagonist, which inhibits phosphodiesterase, 5-lipoxygenase and exhibits antifibrotic, anti-inflammatory activity in preclinical models	2 (5/2018)	NCT0268105
Fecal microbiota transplantation <sup>c</sup>	Modulator of intestinal microbiome	1 (1/2021)	NCT03803540

IMM-124E <sup>c</sup>	IgG-rich extract from cows immunized against lipopolysaccharide, which reduces the hepatic exposure to gut-derived bacterial products	2 (12/2019)**	NCT03042767
GR-MD-02 <sup>d</sup>	Galectin-3 inhibitor, resulting in improvement in liver histology with a significant reduction in NASH activity and collagen deposition	2 (9/2016)	NCT02421094

\* estimated date (month/year) of primary completion

\*\* pediatric clinical trial

Categories: a. *Liver steatosis*, b. *Oxidative stress/inflammation/apoptosis*, c. *Gut microbiota*, d. *Anti-fibrotics*

Abbreviations: FXR; farnesoid X receptor, IR; insulin resistance, NAFLD; nonalcoholic fatty liver disease,

NASH; nonalcoholic steatohepatitis, PPAR; peroxisome proliferator-activator receptors

**Table.** A summary of selected ongoing clinical trials on pediatric NASH. Information has been retrieved by ClinicalTrials.gov as well as by the cited literature